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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,050	02/20/2002	David W. Osborne	359872001400	2420

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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/081,050

Applicant(s)

OSBORNE, DAVID W.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4,7-22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,7-22 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9-15-05</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Receipt of IDS dated 9-15-05 and response dated 9-26-05 is acknowledged.

Claims 1, 4, 7-22 and 25 are pending in the instant application.

The following rejection of record has been maintained:

#### ***Claim Rejections - 35 USC § 102***

1. Claims 1, 4, 7, 13, 14, 20, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,085 to Osborne or US 5,863,560 to Osborne (as evidenced by Russell, AFP, 2000).

Instant claim 1 recites a method for reducing the number of non-inflammatory acne lesions comprising the step of topically applying a composition consists essentially of dapsone. Claim 7 is directed to a method of treating non-inflammatory acne lesions comprising the step as in claim 1.

'085 and '560 discloses topical therapeutic compositions for the treatment of acne. The composition is in the form of semi-solid aqueous gel, where in the pharmaceutical is dissolved and in microparticulate form (col. 2, summary of invention- both '085 and '560). Particularly, Osborne discloses that the composition is effective with dapsone as an active agent (col. 3 of '085 and '560). Examples 2-6 in col. 9-11 (both the references) recite compositions containing dapsone, with other cosmetic additives such as methylparaben, which reads on claimed preservative. Table 1 (col. 13, both patents) recite 3% dapsone concentration. Both references disclose dapsone in a topical composition and for the same purpose i.e., treatment of acne.

Russell teaches that acne, usually diagnosed by the patient, is of three type i.e., inflammatory acne, non-inflammatory acne or a mixture of both (inflammatory and non-inflammatory) types and that the most common situation of acne is a mixture of both inflammatory and non-inflammatory (page 3, clinical manifestations & Figure 5, management of acne on page 10). While '085 and '560 does not disclose treatment of non-inflammatory acne, nothing in the above references indicate that acne (treated by Dapsone of '060 or '560) is not the commonly occurred form (as taught by Russell) and that the acne lesions are only of inflammatory type. Accordingly, both inflammatory and non-inflammatory lesions are inherent to the acne described in the teachings of '060 and '560 and therefore the claimed method of reducing the number of non-inflammatory lesions and the treatment of non-inflammatory lesions of acne is inherent to the teachings of '060 and '560.

2. Claims 8-12, 15-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,060,085 in view of Russell and US 6,200,964 to Singleton et al OR over and US 5,863,560 ('560) in view of Russell and US 6,200,964 to Singleton et al.

'060 and '560 fail to teach the claimed cream, lotion, spray, suspension and ointment formulations. The above references also fail to teach 5% dapsone. Russell suggests preparation of acne treatment formulations in the form of a gel, ointment or cream depending on the patient's skin type (page 3).

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'964 teach acne treatment composition comprising salicylic acid as an active agent for the treatment and prevention of acne (col. 1). '964 teach addition of active agents such as sunscreens, antioxidants, fragrances etc., (col. 4) and teach the composition in the form of spray, cream, lotion, suspension, gel etc (col. 7, lines 20-31). '964 further teach addition of dermatologically active agent such as dapsone in the composition. It would have been obvious to one of an ordinary skill in the art at the time of the instant invention to prepare the dapsone compositions of '060 or '560 in the form of a spray, lotion or a cream or an ointment, depending the type of the skin of the patient being treated because '964 teaches acne preparations in any of the above forms and Russell suggests creams are appropriate for dry skin, gels for oily skin, lotions for any skin type and solutions for dissolved topical antibiotics. Accordingly, it would have been within the scope of a skilled artisan to optimize the amount of dapsone (of '060 and '560) and choose the type of the formulation i.e., a gel or a lotion or a cream etc., depending on the type of skin and also depending on the solubility of the compound, with an expectation to achieve the desired effect (treatment of acne lesions- both types).

### ***Response to Arguments***

Applicant's arguments filed 9-26-05 have been fully considered but they are not persuasive.

Applicants argue that a claim is anticipated only if each and every element in the claim is found either expressly or inherently described, in a single prior art reference; that anticipation rejection that is based on inherency must be supported factual and technical grounds establishing that the inherent feature must flow as a necessary

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conclusion not simply a possible conclusion, from the teaching of cited prior art. In response to this argument, it is to be noted that the property of treating non-inflammatory acne is inherent to Dapsone taught by Osborne (both the references '560 and '085) and the inherent ability of Dapsone to treat non-inflammatory acne comes from the reference of Russell. Thus, the cited prior art meet the requirement to establish inherency.

Applicants argue that examiner is incorrect that nothing in Osborne indicates that the acne being treated is not the most common form (mixed non-inflammatory and inflammatory) and that nothing in Osborne indicates that the acne being treated is only inflammatory acne. In support of this, applicants cite portions of Osborne teachings at columns 1 and 2, particularly the statement of Osborne that " a need exists for acne treatment that maximizes antimicrobial drug level in the upper third of the pilosebaceous unit", which applicants argue emphasizes inflammatory acne. Thus, applicants conclude that when read in entirety it is clear that Osborne is treating only inflammatory acne and hence there is no inherency for the claimed invention. Applicants' arguments are not persuasive because Osborne teaches that the treatment of acne is effective with an antimicrobial compound delivered primarily into the pilosebaceous unit. It is in addition to this, antimicrobial treatment that Osborne teaches anti-inflammatory treatment for acne. Thus, it is clear that antimicrobial and anti-inflammatory actions of dapsone need not be the same and that the antimicrobial action of dapsone need not necessarily be related to anti-inflammatory activity and hence can be considered as non-inflammatory. In addition, Osborne generally describes anti-inflammatory efficacy of dapsone, the

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patent does not define the entire scope of acne and does not differentiate between the types of acne i.e., inflammatory and non-inflammatory. However, the lack of such differentiation does not necessarily mean absence of other stages or types of acne. The fact that acne constitutes inflammatory as well as non-inflammatory types is evidenced by the teachings of Russell. Examiner notes that applicants did not argue the teachings of Russell. Furthermore, instant method uses the same active compound and the irrespective prior art recognition, the property of a compound is inherent is inseparable from the compound and applicants failed to show that dapsone of Osborne patents do not necessarily or inherently possess the ability to treat non-inflammatory acne. Further, applicants also failed to show that the acne lesions being treated in the patient population of Osborne is affected only with inflammatory acne and does not comprise any non-inflammatory lesions as a mixture with inflammatory lesions. Therefore, the examiner maintains the position that dapsone taught by Osborne inherently possesses the ability to treat non-inflammatory acne as claimed in the instant application. With respect to the rejection of claims 8-12 and 15-19 as being unpatentable over Osborne in view of Russell and Singleton, applicants

With respect to the rejection of claims 8-12 and 15-19 as being unpatentable over Osborne in view of Russell and Singleton, applicants argue that examiner implicitly carried over the inherency argument. Applicants argue that all the claimed elements are not disclosed by the cited documents alone or in combination and that a routineer would not have any motivation to use the combined disclosures for treating non-inflammatory acne or for reducing the number of non-inflammatory acne lesions. However, for the

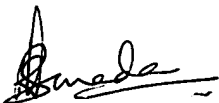
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reasons explained above, the property or the ability to treat non-inflammatory acne is inherent to the composition of dapsones of Osborne. The motivation to prepare the composition in the form of gels, lotions etc., depending on the skin type being treated comes from the teachings of Russell and also from the teachings of Singleton.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615

November 29, 2005